

### **REMARKS**

Claims 56-58, 61-65, 67-76, and 78-81 are pending in the application. Claims 56, 71 and 78 are independent.

Claims 56, 71 and 78 have been amended to include the following limitations, “capable of a detectable tooth-bleaching effect within 30 minutes” and “with a pH between 7-10” support for which can be found in the specification. No new matter has been added.

Claim 56 has been amended to include the limitation of “at least 10%” support for which can be found in the specification. No new matter has been added.

Claims 71 and 78 have been amended to include the limitation of “at least 10% of a” support for which can be found in the specification. No new matter has been added.

Claims 58 and 67-69 have been cancelled.

Reconsideration and favorable action are respectfully requested. Applicant respectfully traverses the rejection.

### **RESPONSE**

#### **Claim Rejections - 35 USC § 103 - Obviousness (New Rejection)**

1) Claims 56-58, 61, 63, 64, 67-73, 75, 76, 78, 80 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al. (US 5,085,853) in view of Collin et al. (US 5,033,650). Applicant respectfully traverses the rejection.

Williams et al. disclose two part oral compositions wherein one part comprises peroxide or a peroxide releasing component and the second part comprises bicarbonate. The compositions are formulated into gels and pastes and may be kept isolated in a separate compartment of a dispenser such as those disclosed by Schaeffer (US 4,849,213), which shows a dispenser comprising a compartment where the two components mix before being dispensed from the dispenser (Fig. 1 of Schaeffer). The mixture of the two components will provide a composition with a pH ranging from 7.0 to 9.5 (col. 4, lines 3-9). The peroxide releasing component includes an alkali metal percarbonate. The compositions may also comprise tartar control agents such as disodium pyrophosphate (col. 4, lines 47-58). Humectants include polyethylene glycol and may comprise 25 to 90% by weight and water may comprise 3 to 30% by weight. The reference differs from the instant claims insofar as it does not disclose the dispensers comprise a static mixer.

Collin et al disclose a multiple barrel dispensing device for intermixing at least two viscous materials and for dispensing the mixed product in a preferred volumetric ratio. The device comprises a syringe having a plurality of elongated storage compartments for independently storing the material to be intermixed and a common head having a separate channel extending from each compartment for discharging stored materials from a common discharge end of said head (col. 2, lines 8-10). It further comprises a nozzle having a common static mixing element. The reference differs from the instant claims insofar as it does not disclose the compositions recited in the instant claims.

In the present invention, independent claims 56, 71 and 78 go to a dosage delivery unit which delivers a 2-component tooth bleaching mixture. The 2 components of the tooth bleaching mixture are kept separated and mixed just prior to leaving the dosage delivery device. One component has at least 10% of hydrogen peroxide containing compound and the second component has an alkaline pH adjusting agent and a stabilizing agent. The mixed composition will provide a tooth whitening affect within 30 minutes of application.

While Williams does disclose the use of a pH adjusting agent, specifically sodium bicarbonate, Williams does not disclose the use of a stabilizing agent or an equivalent. The stabilizing agent has the effect of complexing metal ions in the solution such that metal ions remain in the solution and do not precipitate out. By keeping the metal ions in solution, it prevents precipitated metal from interfering with the whitening process.

Not only does Williams fail to suggest the use of a stabilizing agent, the peroxygen concentrations that it cites are too low to provide effective tooth whitening within 30 minutes without the stabilizing agent. It is commonly known in the art that peroxygen describes a group of compounds which contains two oxygen molecules bound with a double bond. Examples of which includes hydrogen peroxide and carbamide peroxide. In the Williams specification, Williams teaches that lower peroxygen content is preferred. Namely, Williams claims, "0.1 to 10%" peroxygen content, with a preferred concentration of 0.8% to 1.8% (col. 3, lines 29-30) and an optimum concentration of about 1% to 1.5% (col 3, line 30).

On the other hand, claims 56, 71 and 78 of the present invention are amended to claim a hydrogen peroxide content of at least 10%. Support for the amendment can be found in the specification and no new matter has been added. Applicant points out that Williams teaches lower concentrations of peroxygen content while the present invention discloses and claims

compositions with higher concentration of hydrogen peroxide than the maximum concentration of Williams.

Because Williams teaches that lower concentrations of peroxygen is preferred, the composition that Williams discloses should have little tooth whitening effect within 30 minutes, if any tooth whitening effect at all. Examples 4 and 5 in the present application demonstrate that Opalescence, which contains 10% carbamide peroxide and does not have a chelating agent, exhibits "poor performance with regard to color change over the time of the experiment." Meanwhile, the present invention claims a hydrogen peroxide content of greater than 10%, and Examples 4 and 5 show that the combination of hydrogen peroxide content greater than 10% with a chelating agent exhibits superior performance over that of the Opalescence.

The Opalescence at 10% carbamide peroxide has a much greater amount of carbamide peroxide content than the optimum concentration of peroxygen disclosed by Williams, which is 1% to 1.5% (col. 3, line 30), the whitening effect will be even poorer. Therefore, if Opalescence exhibited poor performance compared to the present invention at 10% carbamide peroxide, it can be inferred that at Williams' optimum concentration of peroxygen, the whitening performance of Williams will be even poorer.

Applicant respectfully points out that Examiner concedes that Collin does not disclose the compositions recited in the present application. As a result, Applicant respectfully submits that Collin does not overcome the aforementioned deficiencies in Williams to render the present invention unpatentable.

Claims 57-58, 61, 63, 64, 67-70, 72-3, 75, 76, 80 and 81 are dependent from claims 56, 71 and 78, respectively, and are also rejected under 35 U.S.C. 103(a) as being unpatentable over Williams in view of Collin. While Applicant does not acquiesce with the particular rejections to dependent claims, it is believed that these rejections are moot in view of the remarks made in connection with independent claims 56, 71, and 78. These dependent claims include all of the limitations of the base claims and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Therefore, dependent claims 57-58, 61, 63, 64, 67-70, 72-3, 75, 76, 80 and 81 are also in condition for allowance.

As discussed in the foregoing, Applicant respectfully submits that because Williams teaches away from the present invention, combining Williams in view of Collin does not render the present invention unpatentable. Therefore, Applicant respectfully requests that the rejection

of claims 56-57, 61, 63, 64, 70-73, 75, 76, 78, 80 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al. (US 5,085,853) in view of Collin et al. (US 5,033,650) be withdrawn. Reconsideration is respectfully requested.

2) Claims 62, 75 and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al. (US 5,085,853) in view of Collin et al. (US 5,033,350) as applied to claims 56-58,61,63,64,67-73,75,76,78,80 and 81 in further view of Burke et al. (US 5,292,502). Applicant respectfully traverses the rejection.

The primary and secondary references, Williams et al. and Collin et al. are discussed above. As discussed in the foregoing, Williams in view of Collin does not render the present invention unpatentable. Furthermore, Applicant respectfully submits that the inclusion of Burke to the combination of Williams and Collin does not supply the deficiencies in order to render the present invention unpatentable.

Burke et al. discloses non-irritating dentifrices and is used a general teaching to disclose agents used to adjust pH to 4.5 to 9. These include sodium hydroxide, sodium citrate, benzoate, carbonate or bicarbonate. The reference differs from the instant claims in so far as it does not disclose a two part composition wherein one part comprises a hydrogen peroxide containing compound.

Burke teaches a group of compounds which can be used to adjust the pH in the range of 4.5 to 9. The pH adjusting activity of the compounds disclosed in Burke are known in the art and some of compounds disclosed in Burke are also disclosed in the present application. Sodium hydroxide is one such compound disclosed in both Burke and the present invention. In addition, the present application discloses sodium carbonate and potassium carbonate, which are salt variations of carbonate referenced in Burke.

While Burke does disclose the use of certain compounds to control the pH, these compounds and their utility are already known in the art. Furthermore, Burke does not disclose the use of the stabilizing agent or hydrogen peroxide in a concentration that is sufficiently high enough to generate a tooth whitening effect in 30 minutes or less.

In addition, Burke does not supply the deficiencies of Williams and Collin. Therefore, claims 56, 71 and 78 are patentable. Claims 62, 75 and 79 are dependent from claims 56, 71 and 78, respectively, and are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams in

view of Collin as applied to claims 56-58,61,63,64,67-73,75,76,78,80 and 81 in further view of Burke. While Applicant does not acquiesce with the particular rejections to dependent claims, it is believed that these rejections are moot in view of the remarks made in connection with independent claims 56, 71, and 78. These dependent claims include all of the limitations of the base claims and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Therefore, dependent claims 62, 75 and 79 are also in condition for allowance for at least the same reasons as noted for claim 56, 71 and 78.

Reconsideration is respectfully requested.

3} Claims 56-57, 61-65, 67-76 and 78-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Viscio (US 5,302,375) in view of Collin et al. (US 5,033,650). Applicant respectfully traverses the rejection.

Viscio discloses compositions comprising sodium percarbonate in a non-aqueous carrier. The composition may be formulated into two parts wherein the first part is a nonaqueous composition comprising a percarbonate and the second part is an aqueous composition comprising acetylsalicylic acid. The compositions comprise 40 to 70% water (col. 4, lines 60-63). The mixing of the two components will result in a mixture have a pH of less than 10 and generally in the range of from about 8.0 to about 9.0 (col. 3, lines 60-65). The pH of the acid comprising component may be adjusted to 5.0 to about 6.5 with components such as citric acid (col. 4, lines 1-6). The pH of the acid comprising component may be adjusted to below 7.0, preferably 5.0 to 6.5 (col. 3, line 68 to col. 4, line 1). The reference also discloses using sodium hydroxide to adjust comparative compositions comprising acid to increase the pH. Gelling agents such as Carbopol 941 (Example 5) are also used in the formulations and polyethylene glycol is included as a humectant. Other components include anti-tartar agents such as tetra sodium pyrophosphate (which is also a base) and dialkali metal pyrophosphates, and peroxide stabilizers such as ethylenediaminetetraacetic acid, diethylene triaminepentaacetic acid, phosphonates such as DEQUEST (col. 6, lines 9-30). water, it rapidly releases hydrogen peroxide (col. 2, lines 48-55). Drucker, US 4,895,721 discloses tetra sodium pyrophosphate is a base that may be used to adjust pH (col. 3, lines 9-14). The reference differs from the instant claims insofar as it does not disclose the dispensers comprise a static mixer.

Viscio discloses a different whitening system from hydrogen peroxide. It discloses “an oral composition for whitening teeth comprising a safe and effective whitening amount of peracetic acid dissolved or suspended in a vehicle, wherein the peracetic acid is generated within the vehicle in situ by combining water, acetylsalicylic acid and a water soluble alkali metal percarbonate.” See Abstract. (Emphasis added)

Applicant respectfully submits that because Viscio is using a different whitening system based on the generation of peracetic acid, Viscio has the effect of teaching away from the present invention.

In Viscio teeth are whitened through the generation of peracetic acid. As such, because Viscio is using an acid to whiten teeth, it utilizes acids for pH adjustment and the resulting composition is acidic. On the other hand, the present invention uses bases for pH adjustment, which creates a composition that is alkaline. According to Viscio, pH adjustment is done using, “any non-toxic acid or acid salt” (col. 4, lines 1-3) whereas the present invention makes use of “alkaline pH adjusting agent...” (claim 56)

The resulting disparity of utilizing acids versus bases for pH adjustment is more clearly seen in the pH ranges contained within the specification. In Viscio, the claimed pH is 7 or below. The desired pH range is about 5.0 to 6.5. (col. 4, line 1).

On the other hand, claims 56, 71 and 78 of the present invention are amended to claim a pH range of 7-10. Support for this amendment can be found in the specification and no new matter has been added. Applicant points out that Viscio teaches an acidic whitening composition, while the present invention discloses and claims an alkaline whitening composition. In the present invention, the whitening composition is in pH range is between 7-10, but with whitening being more effective when the pH is in the range of 8-9.5. (paragraph 23). Based on the disclosed pH ranges, Viscio is clearly targeting a lower pH range than the present invention.

Therefore, Viscio teaches away from the present invention because it discloses a completely different approach to a whitening composition than the present invention. Furthermore, as discussed above, Collin does not supply the deficiencies of Viscio to render the present invention unpatentable.

Applicant respectfully points out that Examiner concedes that Collin does not disclose the compositions recited in the present application. As a result, Applicant respectfully submits that

Collin does not overcome the aforementioned deficiencies in Williams to render the present invention unpatentable.

Applicant respectfully requests that the rejection of claims 56-57, 61, 63, 64, 70-73, 75, 76, 78, 80 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Viscio (US 5,302,375) in view of Collin et al. (US 5,829,639) be withdrawn. Reconsideration is respectfully requested.

### **CONCLUSION**

The applicant believes that this Amendment addresses all of the points raised in the Office Action, and requests reconsideration and allowance of the present application, with pending claims 56-57, 61-65, 70-76, and 78-81.

If a telephone conference would be helpful in resolving any issues concerning this communication, please contact the undersigned at 310-845-8312.

Dated: April 22, 2009

Respectfully submitted,

/Frederick W. Tong/

Frederick W. Tong, Esq.  
Reg. 55680  
Discus Dental, LLC  
8550 Higuera Street  
Culver City, California 90232  
Direct Line: 310-845-8312  
Facsimile: 310-845-1513  
[fredt@discusdental.com](mailto:fredt@discusdental.com)